

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

**ELIZABETH KLEIN and  
HARRY KLEIN, her husband,**

**Plaintiffs,**

**Civil Action No.: 08-CV-4157**

**vs.**

**MERCK & CO., INC.,**

**Defendant.**

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**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs, ELIZABETH KLEIN and HARRY KLEIN, her husband, through their undersigned attorneys ASHCRAFT & GEREL, LLP, sue Defendant Merck & Company, Inc., and allege as follows:

**I. JURISDICTION AND VENUE**

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiffs and Defendant. Plaintiffs are residents of the state of New York, and Defendant is incorporated and has as its primary business in the state of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

## **II. PARTIES**

3. Plaintiff Elizabeth Klein was born October 21, 1926. Plaintiff used FOSAMAX from approximately 1997 until approximately 2005. Plaintiff Elizabeth Klein was married to Harry Klein and they were residents of the state of New York at all times material to this action.
4. Defendant is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.
5. Defendant was at all relevant times authorized to conduct business in the state of New York.
6. Defendant has regularly transacted business in the state of New York and continues to do so.
7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.
8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the state of New York for the treatment of osteoporosis, Paget's Disease and other off-label uses.

9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the state of New York.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the state of New York.

### **III. SUMMARY OF THE CASE**

11. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.
12. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff Elizabeth Klein, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.
13. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff Elizabeth Klein, other consumers, and the medical community.
14. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
15. As a result of Defendant's actions and inaction, Plaintiff Elizabeth Klein was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

#### **IV. FACTUAL BACKGROUND**

16. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
17. In September 1995, the United States Food and Drug Administration (“FDA”) approved Merck’s compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget’s Disease.
18. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget’s disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
19. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (Actonel); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

20. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw with the use of nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared an adverse event profile similar to that of the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).
21. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
22. Merck also knew or should have known these factors combine to create a compromised vascular supply to the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
23. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.
24. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

25. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.
26. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
27. Since FOSAMAX was released, the FDA has received a number of reports of osteonecrosis of the jaw among users of FOSAMAX.
28. On August 25, 2004, the FDA posted its Office of Drug Safety ("ODS") Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.
29. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that osteonecrosis of the jaw was a class effect that specifically extended to the oral bisphosphonate FOSAMAX.

30. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.
31. Rather than warn patients, and despite Defendant's knowledge of an increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.
32. FOSAMAX is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.
33. Consumers, including Plaintiff Elizabeth Klein, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.
34. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff Elizabeth Klein, or the medical community, of such risks.
35. In the design, manufacture, labeling, and marketing of FOSAMAX, the Defendants engaged in numerous acts that constituted violations of federal statutes and regulations, including but not limited to:
  - a. The labeling lacked adequate information on the use of the drug Fosamax® (21 C.F.R. Section 201.56(a) and (d));

- b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drug (21 C.F.R. 201.57(e));
- c. There was inadequate information for patients for the safe and effective use of Defendant's drug (21 C.F.R. 201.57(f)(2));
- d. There was inadequate information regarding special care to be exercised by the Plaintiff's doctors for safe and effective use of Defendant's drug (21 C.F.R. 201.57(f)(1));
- e. The labeling was misleading and promotional (21 C.F.R. 201.56(b)); and
- f. Defendant's acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

36. As a direct result, Plaintiff Elizabeth Klein was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Elizabeth Klein requires and will in the future require ongoing medical care and treatment for the injuries she suffered as a result of taking FOSAMAX.

37. Plaintiff Elizabeth Klein has suffered mental anguish as a result of knowing the life-long complications she will suffer as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

38. Plaintiff Elizabeth Klein was prescribed and began taking FOSAMAX in approximately 1997. She was diagnosed with osteonecrosis of the jaw on or about March of 2006.



39. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.
40. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury.
41. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and has sustained permanent injuries and emotional distress.
42. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
43. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.
44. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.
45. As a result of Defendant's actions, Plaintiff and her prescribing and treating physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

**V. COUNTS**

**COUNT I: NEGLIGENCE**

46. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
47. Defendant owed Plaintiff, Elizabeth Klein, other consumers, and physicians a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
48. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:
  - a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;
  - b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;
  - c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
  - d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
  - e. failing to exercise due care when advertising and promoting FOSAMAX; and
  - f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.
49. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent

injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

50. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
51. Plaintiff Elizabeth Klein's spouse, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.
52. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which

were violated by the Defendant.

COUNT II: STRICT LIABILITY

53. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
54. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Elizabeth Klein.
55. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
56. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.
57. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.
58. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
59. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.
60. FOSAMAX was defective in its design and was unreasonably dangerous in that it

neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, and or physicians, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

61. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.
62. Plaintiff and or her physician(s) could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.
63. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss

of wages and wage-earning capacity.

64. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
65. Plaintiff Elizabeth Klein's spouse, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.
66. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

### COUNT III: BREACH OF EXPRESS WARRANTY

67. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
68. Defendant expressly represented to Plaintiff Elizabeth Klein and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.
69. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent

injuries.

70. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
71. Plaintiff Elizabeth Klein, other consumers, and the medical community relied upon Defendant's express warranties.
72. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
73. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

74. Plaintiff Elizabeth Klein's spouse, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.
75. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT IV: BREACH OF IMPLIED WARRANTY

76. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
77. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.
78. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
79. Defendant was aware that consumers, including Plaintiff Elizabeth Klein, would use FOSAMAX for treatment of osteoporosis or Paget's Disease and for other off-label purposes.
80. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.
81. Defendant breached its implied warranty to consumers, including Plaintiff;



FOSAMAX was not of merchantable quality or safe and fit for its intended use.

82. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.
83. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.
84. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
85. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

86. Plaintiff Elizabeth Klein's spouse, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.
87. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT V: FRAUDULENT MISREPRESENTATION

88. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
89. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:
- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's Disease; and
  - b. Defendant represented that FOSAMAX was safer than other alternative medications.
90. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

91. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
92. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.
93. Plaintiff Elizabeth Klein, Plaintiff's doctors, and others relied upon the representations.
94. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
95. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss

of wages and wage-earning capacity.

96. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
97. Plaintiff Elizabeth Klein's spouse, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.
98. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

#### COUNT VI: FRAUDULENT CONCEALMENT

99. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
100. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:
  - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

- b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.
101. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.
102. Defendant's concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.
103. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
104. Plaintiff Elizabeth Klein, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.
105. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Elizabeth Klein sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and

damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

106. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

107. Plaintiff Elizabeth Klein 's husband, Harry Klein, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

108. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant, as follows:

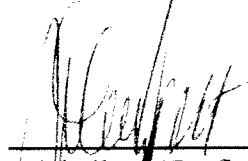
- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;
- c. reasonable attorneys' fees where recoverable;

- d. costs of this action; and
- e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

**VI. DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury on all counts and issues so triable.

ASHCRAFT & GEREL, LLP



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Michelle A. Parfitt, Esq.

(Order granting admission *pro hac vice* for MDL 1789 is attached)

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*Attorneys for Plaintiffs*

JS 44C/SDNY  
REV. 12/2005

## CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS ELIZABETH KLEIN and  
HARRY KLEIN

DEFENDANTS MERCK & CO., INC.

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER) ASHCRAFT & GEREL, LLP, 2000 L STREET, NW  
SUITE 400, WASHINGTON, DC 20036

ATTORNEYS (IF KNOWN) Michelle A. Parfitt

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)

28 U.S.C. 1332  
PRODUCT LIABILITY - DEFECTIVE PHARMACEUTICAL (Fosamax)

Has this or a similar case been previously filed in SDNY at any time? No ☐ Yes? ☒ Judge Previously Assigned KEENAN

If yes, was this case Vol ☐ Invol. ☐ Dismissed. No ☒ Yes ☐ If yes, give date \_\_\_\_\_ & Case No. \_\_\_\_\_

(PLACE AN [x] IN ONE BOX ONLY)

## NATURE OF SUIT

## ACTIONS UNDER STATUTES

TORTS			FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<b>CONTRACT</b>	<b>PERSONAL INJURY</b>	<b>PERSONAL INJURY</b>	<input type="checkbox"/> 610 AGRICULTURE	<input type="checkbox"/> 422 APPEAL	<input type="checkbox"/> 400 STATE
<input type="checkbox"/> 110 INSURANCE	<input type="checkbox"/> 310 AIRPLANE	<input type="checkbox"/> 362 PERSONAL INJURY -	<input type="checkbox"/> 620 FOOD & DRUG	<input type="checkbox"/> 28 USC 158	<input type="checkbox"/> REAPPORTIONMENT
<input type="checkbox"/> 120 MARINE	<input type="checkbox"/> 315 AIRPLANE PRODUCT	MED MALPRACTICE	<input type="checkbox"/> 625 DRUG RELATED	<input type="checkbox"/> 423 WITHDRAWAL	<input type="checkbox"/> 410 ANTITRUST
<input type="checkbox"/> 130 MILLER ACT	LIABILITY	<input checked="" type="checkbox"/> 365 PERSONAL INJURY	SEIZURE OF	<input type="checkbox"/> 28 USC 157	<input type="checkbox"/> 430 BANKS & BANKING
<input type="checkbox"/> 140 NEGOTIABLE	<input type="checkbox"/> 320 ASSAULT, LIBEL &	PRODUCT LIABILITY	PROPERTY		<input type="checkbox"/> 450 COMMERCE/ICC
INSTRUMENT	SLANDER	<input type="checkbox"/> 368 ASBESTOS PERSONAL	21 USC 881	<b>PROPERTY RIGHTS</b>	<input type="checkbox"/> RATES/ETC
<input type="checkbox"/> 150 RECOVERY OF	<input type="checkbox"/> 330 FEDERAL	INJURY PRODUCT	<input type="checkbox"/> 630 LIQUOR LAWS	<input type="checkbox"/> 820 COPYRIGHTS	<input type="checkbox"/> 460 DEPORTATION
OVERPAYMENT &	EMPLOYERS'	LIABILITY	<input type="checkbox"/> 640 RR & TRUCK	<input type="checkbox"/> 330 PATENT	<input type="checkbox"/> 470 RACKETEER INFLU-
ENFORCEMENT OF	LIABILITY	<b>PERSONAL PROPERTY</b>	<input type="checkbox"/> 650 AIRLINE REGS	<input type="checkbox"/> 840 TRADEMARK	ENCED & CORRUPT
JUDGMENT	<input type="checkbox"/> 340 MARINE	<input type="checkbox"/> 370 OTHER FRAUD	<input type="checkbox"/> 660 OCCUPATIONAL		ORGANIZATION ACT
<input type="checkbox"/> 151 MEDICARE ACT	<input type="checkbox"/> 345 MARINE PRODUCT	<input type="checkbox"/> 371 TRUTH IN LENDING	<input type="checkbox"/> 690 OTHER	<b>SOCIAL SECURITY</b>	<input type="checkbox"/> 480 CONSUMER CREDIT
<input type="checkbox"/> 152 RECOVERY OF	LIABILITY	<input type="checkbox"/> 380 OTHER PERSONAL	<b>LABOR</b>	<input type="checkbox"/> 861 MIA (1395FF)	<input type="checkbox"/> 490 CABLE/SATELLITE TV
DEFAULTED	<input type="checkbox"/> 350 MOTOR VEHICLE	PROPERTY DAMAGE	<input type="checkbox"/> 710 FAIR LABOR	<input type="checkbox"/> 862 BLACK LUNG (923)	<input type="checkbox"/> 810 SELECTIVE SERVICE
STUDENT LOANS	<input type="checkbox"/> 355 MOTOR VEHICLE	PRODUCT LIABILITY	<input type="checkbox"/> 720 STANDARDS ACT	<input type="checkbox"/> 863 DIWC (405(g))	<input type="checkbox"/> 850 SECURITIES/
(EXCL VETERANS)	PRODUCT LIABILITY	<input type="checkbox"/> 385 PROPERTY DAMAGE	LABOR/MGMT	<input type="checkbox"/> 864 DIWW (405(g))	COMMODITIES/
<input type="checkbox"/> 153 RECOVERY OF	<input type="checkbox"/> 360 OTHER PERSONAL	PRODUCT LIABILITY	RELATIONS	<input type="checkbox"/> 864 SSID TITLE XVI	EXCHANGE
OVERPAYMENT OF	INJURY		<input type="checkbox"/> 730 LABOR/MGMT	<input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 875 CUSTOMER
VETERANS BENEFITS			REPORTING &		CHALLENGE
<input type="checkbox"/> 160 STOCKHOLDERS SUITS			DISCLOSURE ACT	<b>FEDERAL TAX SUITS</b>	<input type="checkbox"/> 12 USC 3410
<input type="checkbox"/> 190 OTHER CONTRACT			<input type="checkbox"/> 740 RAILWAY LABOR ACT	<input type="checkbox"/> 870 TAXES	<input type="checkbox"/> 891 AGRICULTURE ACTS
<input type="checkbox"/> 195 CONTRACT PRODUCT			<input type="checkbox"/> 790 OTHER LABOR	<input type="checkbox"/> 871 IRS-THIRD PARTY	<input type="checkbox"/> 892 ECONOMIC
LIABILITY			LITIGATION	<input type="checkbox"/> 20 USC 7609	STABILIZATION ACT
<input type="checkbox"/> 196 FRANCHISE			<input type="checkbox"/> 791 EMPL RET INC		<input type="checkbox"/> 893 ENVIRONMENTAL
			SECURITY ACT		MATTERS
	<b>ACTIONS UNDER STATUTES</b>	<b>PRISONER PETITIONS</b>			<input type="checkbox"/> 894 ENERGY
<b>REAL PROPERTY</b>	<b>CIVIL RIGHTS</b>	<input type="checkbox"/> 510 MOTIONS TO			ALLOCATION ACT
<input type="checkbox"/> 210 LAND CONDEMNATION	<input type="checkbox"/> 441 VOTING	VACATE SENTENCE			<input type="checkbox"/> 895 FREEDOM OF
<input type="checkbox"/> 220 FORECLOSURE	<input type="checkbox"/> 442 EMPLOYMENT	28 USC 2255			INFORMATION ACT
<input type="checkbox"/> 230 RENT LEASE &	<input type="checkbox"/> 443 HOUSING	<input type="checkbox"/> 530 HABEAS CORPUS			<input type="checkbox"/> 900 APPEAL OF FEE
EJECTMENT	<input type="checkbox"/> 444 ACCOMMODATIONS	<input type="checkbox"/> 535 DEATH PENALTY			DETERMINATION
<input type="checkbox"/> 240 TORTS TO LAND	<input type="checkbox"/> 445 WELFARE	<input type="checkbox"/> 540 MANDAMUS & OTHER			UNDER EQUAL ACCESS
<input type="checkbox"/> 246 TORT PRODUCT	<input type="checkbox"/> 445 AMERICANS WITH	<input type="checkbox"/> 550 CIVIL RIGHTS			TO JUSTICE
LIABILITY	DISABILITIES -	<input type="checkbox"/> 555 PRISON CONDITION			<input type="checkbox"/> 950 CONSTITUTIONALITY
<input type="checkbox"/> 290 ALL OTHER	EMPLOYMENT				OF STATE STATUTES
REAL PROPERTY	<input type="checkbox"/> 446 AMERICANS WITH				<input type="checkbox"/> 890 OTHER STATUTORY
	DISABILITIES - OTHER				ACTIONS
	<input type="checkbox"/> 440 OTHER CIVIL RIGHTS				

Check if demanded in complaint:

CHECK IF THIS IS A CLASS ACTION  
UNDER F.R.C.P. 23DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.?  
IF SO, STATE:

DEMAND \$ \_\_\_\_\_ OTHER \_\_\_\_\_ JUDGE KEENAN DOCKET NUMBER 06-MDL 1789

Check YES only if demanded in complaint

JURY DEMAND: ☒ YES ☐ NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

(SEE REVERSE)



(PLACE AN x IN ONE BOX ONLY)

## ORIGIN

- ☒ 1 Original Proceeding
 ☐ 2a. Removed from State Court
 ☐ 3 Remanded from Appellate Court
 ☐ 4 Reinstated or Reopened
 ☐ 5 Transferred from (Specify District)
 ☐ 6 Multidistrict Litigation
 ☐ 7 Appeal to District Judge from Magistrate Judge Judgment
- ☐ 2b. Removed from State Court
- AND at least one party is a pro se litigant

(PLACE AN x IN ONE BOX ONLY)

## BASIS OF JURISDICTION

IF DIVERSITY, INDICATE  
CITIZENSHIP BELOW.  
(28 USC 1332, 1441)

- ☐ 1 U.S. PLAINTIFF
 ☐ 2 U.S. DEFENDANT
 ☐ 3 FEDERAL QUESTION (U.S. NOT A PARTY)
 ☒ 4 DIVERSITY

## CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

	PTF	DEF		PTF	DEF		PTF	DEF
CITIZEN OF THIS STATE	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	<input type="checkbox"/> 3	<input type="checkbox"/> 3	INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
CITIZEN OF ANOTHER STATE	<input type="checkbox"/> 2	<input type="checkbox"/> 2	INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE	<input type="checkbox"/> 4	<input type="checkbox"/> 4	FOREIGN NATION	<input type="checkbox"/> 6	<input type="checkbox"/> 6

## PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

ELIZABETH KLEIN  
2355 BELL BOULEVARD, APT. J2  
BAYSIDE, NY 11360

HARRY KLEIN  
2355 BELL BOULEVARD, APT. J2  
BAYSIDE, NY 11360

## DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

MERCK & CO., INC.  
ONE MERCK DRIVE  
P.O. BOX 100, WS3AB-05  
WHITEHOUSE STATION, NEW JERSEY, 08889-0100

## DEFENDANT(S) ADDRESS UNKNOWN

REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: ☐ WHITE PLAINS ☒ FOLEY SQUARE  
(DO NOT check either box if this is a PRISONER PETITION.)

DATE	SIGNATURE OF ATTORNEY OF RECORD	ADMITTED TO PRACTICE IN THIS DISTRICT
		<input type="checkbox"/> NO
RECEIPT #		<input checked="" type="checkbox"/> YES (DATE ADMITTED Mo. 4 Yr. 2008)
		Attorney Bar Code # XXXXX

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge \_\_\_\_\_ is so Designated.

J Michael McMahon, Clerk of Court by \_\_\_\_\_ Deputy Clerk, DATED \_\_\_\_\_.

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

# United States District Court

SOUTHERN

DISTRICT OF

NEW YORK

---

ELIZABETH KLEIN, et al.

## SUMMONS IN A CIVIL CASE

V.

CASE NUMBER:

MERCK & CO., INC.

TO: (Name and address of defendant)

MERCK & CO., INC.  
C/O C T CORPORATION SYSTEM  
111 EIGHTH AVENUE  
NEW YORK, NEW YORK, 10011

**YOU ARE HEREBY SUMMONED** and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

MICHELLE A. PARFITT, ESQ.  
ASHCRAFT & GEREL, LLP  
2000 L. STREET, N.W., SUITE 400  
WASHINGTON, DC. 20036

an answer to the complaint which is herewith served upon you, within \_\_\_\_\_ days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

\_\_\_\_\_  
CLERK

\_\_\_\_\_  
DATE

\_\_\_\_\_  
(BY) DEPUTY CLERK

AO 440 (Rev. 10/93) Summons In a Civil Action -SDNY WEB 4/99

<b>RETURN OF SERVICE</b>		
Service of the Summons and Complaint was made by me <sup>1</sup>	DATE	
NAME OF SERVER (PRINT)	TITLE	
<i>Check one box below to indicate appropriate method of service</i>		
<input type="checkbox"/> Served personally upon the defendant. Place where served: _____ _____		
<input type="checkbox"/> Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: _____ _____		
<input type="checkbox"/> Returned unexecuted: _____ _____ _____		
<input type="checkbox"/> Other (specify): _____ _____ _____		
<b>STATEMENT OF SERVICE FEES</b>		
TRAVEL	SERVICES	TOTAL
<b>DECLARATION OF SERVER</b>		
<p style="text-align: center;">I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Executed on _____</p> <p style="text-align: center;">Date</p> </div> <div style="width: 45%;"> <p>_____ Signature of Server</p>   <p>_____ Address of Server</p> </div> </div>		

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

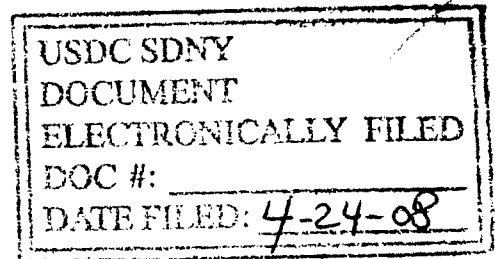
IN RE: Fosamax Products Liability  
Litigation

1:06-MDL-1789 (JFK)

This Document Relates to:

MDL 1789

Civil No.: \_\_\_\_\_



ORDER FOR ADMISSION *PRO HAC VICE*

Upon consideration of the attached Certificate of Good Standing from the Clerk of Court  
for the United States District Court for the District of Columbia, it is hereby ORDERED this

\_\_\_\_\_ day of \_\_\_\_\_, 2008, that

Michelle A. Parfitt  
Ashcraft & Gerel, LLP  
2000 L Street, N.W., Suite 400  
Washington, DC 20036  
Telephone: (202) 783-6400  
Fax: (202) 416-6392

is admitted to practice *pro hac vice* as counsel for the Plaintiffs in the above-referenced MDL  
proceeding.

4/24/08 John F. Keenan  
Judge John F. Keenan

MICROFILMED

APR 25 2008 -12 00 PM